DETAILED ACTION

Status of Claims

1. Claims 1 and 3-10 are pending in this application. Claim 2 stands canceled.

2. Claims 1 and 3-10 are examined.

Priority

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The rejection of claims 1 and 3-10 under 35 USC 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607) and Greenberg (US Patent 5,260,279) is withdrawn in view of Applicant's amendment to claim 1; however, a new grounds of rejection is set forth below.

6. **Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakashima et al (US Patent 5,126,143) in view of Farmer (US Patent 6,461,607) and FR 2244464 ("FR '464"; English abstract and machine**

translation included with this Office action), as evidenced by Lasater et al (US Patent 5,200,218).

The claimed invention, as now amended, is drawn to a food composition for lowering blood concentration of low- molecular-weight nitrogen-containing compounds, which comprises: a foodstuff with a) more than 5% by weight of water-soluble indigestible polysaccharides relative to a total amount of dried foodstuff, said indigestible polysaccharides capable of being decomposed by intestinal bacteria, and b) Bacillus coagulans, said foodstuff having metal-containing yeast of 0.01% to 5.0% by weight and protein component of 8% or less by weight, wherein said metal-containing yeast comprises a metal selected from the group consisting of Mg, Zn, Fe, Cu, Co and Mn (see claim 1).

Nakashima et al teach a bowel-movement-improving food containing 10-50% by weight of dietary fibers based upon the whole product (see claim 1). Nakashima et al. teach foods having more than 5% by weight indigestible polysaccharides; see Example 1, which has 25% dietary fibers (18 parts polydextrose and 6.9 parts pectin, relative to 100.3 total parts). The amount of protein in the food is less than 8%; amounts of 6% and 5.4% casein are exemplified (see, for example, Examples 1 and 4). The dietary fibers are decomposed by intestinal microorganisms (see Examples 1, 4 and 5).

Nakashima et al do not specifically teach the presence of Bacillus coagulans or metal containing yeast of 0.01% to 5% by weight in the food composition.

Farmer teaches the utilization of lactic acid-producing bacteria, preferably Bacillus coagulans, for control of gastrointestinal tract pathogens and their associated

diseases (abstract), and that Bacillus coagulans strains have been used as general nutritional supplements and agents to control constipation and diarrhea in humans and animals (col. 14, lines 50-53).

FR '464 teaches a composition comprising yeast, a lactobacillus, and B vitamins, for treatment of conditions including constipation and digestive disorders; the yeast is preferably Saccharomyces cerevisiae (i.e., Brewer's yeast; see abstract). Brewer's yeast is a metal-containing yeast comprising metals including magnesium, zinc, and iron; as evidence, Lasater et al generally teach that Brewer's yeast includes the nutrients magnesium, zinc, and iron (col. 2, lines 56-63).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to add Bacillus coagulans and metal-containing yeast to the composition of Nakashima et al; thus arriving at the claimed invention. One skilled in the art would have been motivated to add Bacillus coagulans because the addition of Bacillus coagulans provides the benefits of controlling constipation and diarrhea, as taught by Farmer. Additionally, it is prima facie obvious to combine two compositions, each of which is taught by the prior art, to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. See MPEP 2144.06. Additionally, since metal containing yeast is known to be useful in compositions for treating constipation, as taught by FR '464, one skilled in the art would be motivated to add metal containing yeast in order to provide additional nutritional benefits, as well as providing the benefit of treating constipation and other digestive disorders, as taught by FR '464. One would reasonably expect success from the addition of Bacillus coagulans

as taught by Farmer and metal containing yeast as taught by FR '464 to the composition taught by Nakashima et al because all of the references are drawn to improving bowel movements.

Regarding the phrase "for lowering blood concentration of low-molecular-weight nitrogen-containing compounds", said phrase describes an intended use for the food and does not provide any structural limitation to the composition, and thus is not given patentable weight.

Regarding claim 3, Nakashima et al. disclose that dietary fibers which may be used are polydextrose and pectin (see col. 3, lines 20-22 and claim 1).

Regarding claim 4, Nakashima et al. disclose that the food contains a mixture of polydextrose and pectin, wherein said mixture is comprised of 1/2 to 3/4 polydextrose and 1/2 to 1/4 pectin. This reads on Applicant's ratio of 0.05 to 100 parts by weight of pectine to 100 parts of polydextrose.

Regarding claims 5 and 6, Nakashima et al. disclose that the foods may contain vitamins (col. 4, lines 32-38).

Regarding claims 7-10, Nakashima et al. disclose that the food may be in the form of the wafer; the term "wafer" reads on a reasonable interpretation of either "biscuit", "cookie" or "bread".

Response to Arguments

7. Applicant's arguments filed 2/12/09 have been fully considered but are deemed moot in view of the new grounds of rejection. However, the Examiner has responded to those aspects of the arguments that may be applicable to the new rejection.

In response to Applicant's argument that the combination of references does not teach or suggest the limitation wherein the "metal-containing yeast comprises a metal selected from the group consisting of Mg, Zn, Fe, Cu, Co and Mn", as now recited in claim 1, as currently amended, said argument has been considered but is deemed to be moot in view of the new grounds of rejection.

In response to Applicant's argument that Greenberg does not teach that the metal-containing yeast activates intestinal bacteria and "Bacillus coagulans", and that a person of ordinary skill in the art would not have expected the synergistic effect, such that Bacillus coagulans is activated by a metal-containing yeast comprising a metal selected from the group consisting of Mg, Zn, Fe, Cu, Co, and Mn, it is noted that features of synergy and/or activation are not recited in the rejected claims. Instead, the claims are merely drawn to a combination of the components of water-soluble indigestible polysaccharide, Bacillus coagulans, and metal-containing yeast; as recited in amended claim 1, this combination of components met by the combination of references, as set forth below. Furthermore, one skilled in the art would reasonably expect said activation and/or synergy, since the same components and amounts of the claimed invention are present in the composition of the combined references. The Examiner further notes that Applicant's specification does not teach that Bacillus

coagulans is activated by a metal-containing yeast comprising a metal selected from the group consisting of Mg, Zn, Fe, Cu, Co and Mn, nor that there is a synergistic effect from the combination of components; therefore, such a limitation, if added to the claims, would be considered new matter.

Conclusion

No claims are allowed at this time.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

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